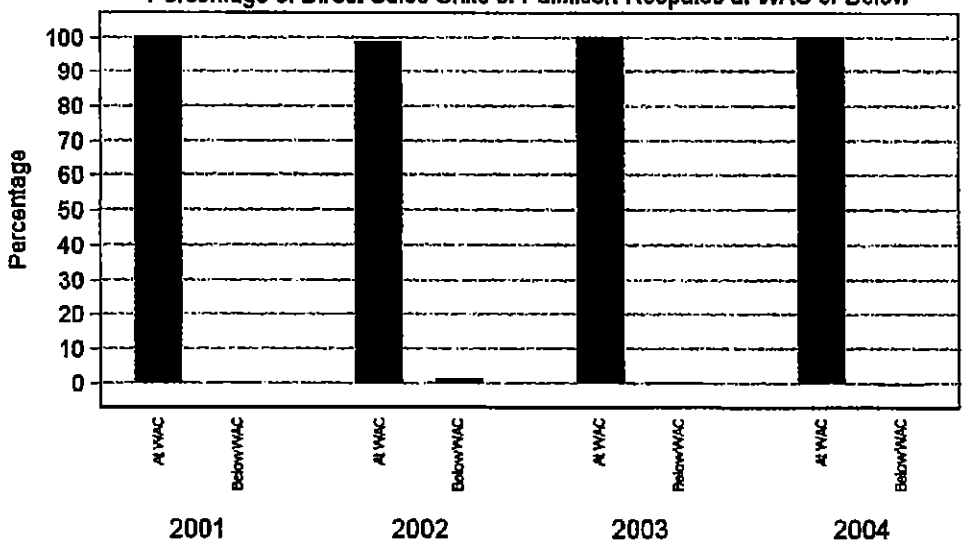
proposed marketing strategy was to "[m]ake PR the controller therapy of choice for treating asthmatic infants and children who are not controlled on bronchodilators alone and require daily anti-inflammatory therapy."[28] As shown in Figure 5, virtually all sales of Pulmicort Respules were made at or close to WAC.[29]

Figure 5
Percentage of Direct Sales Units of Pulmicort Respules at WAC or Below



Note: Classes 3, 5 and 8 represent Government and Hospitals and are excluded.
Source: AZ Pulmicort Respules Direct Sales (AZ0455414).

63. The market for Pulmicort Respules differs in several critical ways from the market for PADs generally and for the drugs for which most reimbursement is made under Medicare Part B:

- Most patients are children, not Medicare-eligible;
- In fact, there was no J-code assigned until 2002;
- Most prescriptions are dispensed through pharmacies, not in doctors' offices;

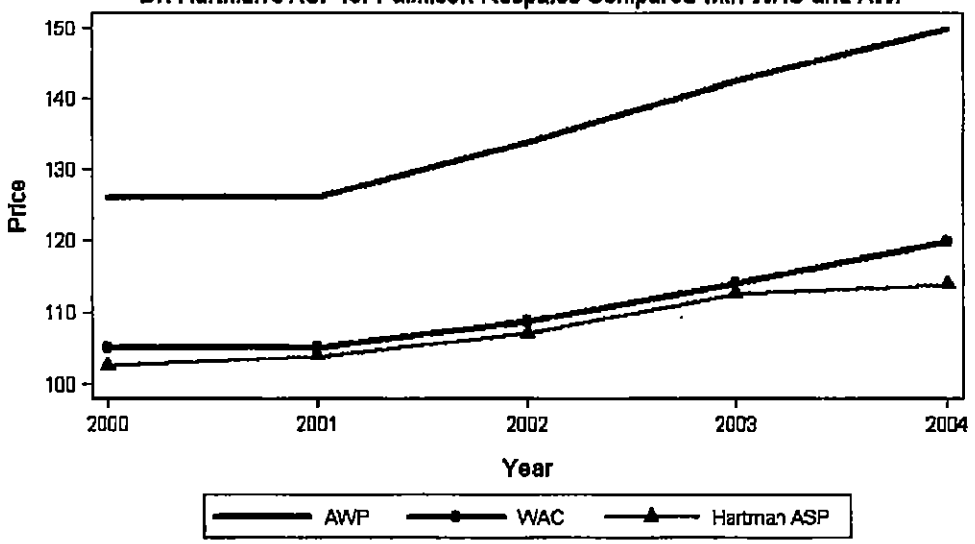
[28] "Pulmicort Respules Fact Pack," February 19, 1999 (AZ0444872-932, AZ0444880).
[29] The year 2000 was excluded because the data only covers September to December.

- For an important segment of users (children under 2) there is no significant nebulized therapeutic competition;
- The product was launched only recently (and assigned a J-code even later), when there was already substantial publicity (from the Complaint, government studies, etc.) about the alleged "AWP inflation."

B. PRICING AND DISCOUNTING OF PULMICORT RESPULES

64. Figure 6 shows the WAC, AWP and ASP (calculated by Dr. Hartman) for Pulmicort Respules from 2000-2004. Throughout this period, ASP was very close to WAC, increasing whenever AstraZeneca increase WAC. The "spread" never exceeded 30 percent, and did not grow over this period. Thus, there was no "inflation" in AWP by increasing AWP while holding ASP constant.

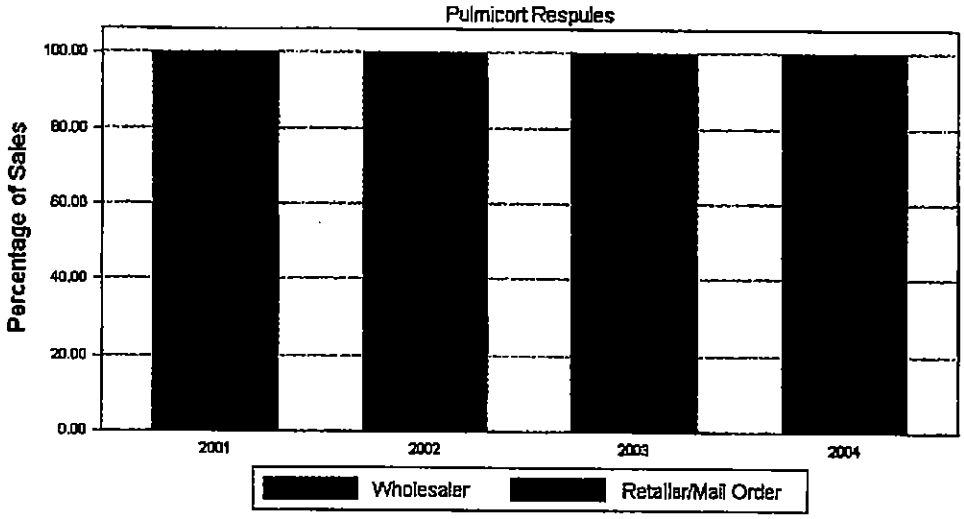
Figure 6
Dr. Hartman's ASP for Pulmicort Respules Compared with WAC and AWP



Note: Classes 3, 5 and 8 represent Government and Hospitals and are excluded.
Source: First Data Bank and Dr. Hartman's 2/23/06 Addendum

65. Figure 7 shows the distribution of direct sales of Pulmicort Respules by trade class. Most direct sales are to wholesalers, with a small fraction to pharmacies (chains and independents). There are no direct sales to doctors or clinics.

Figure 7
Distribution of Direct Sales by Trade Class



Note: Excludes Trade Class 3, 5 and 8 which represent Government and Hospitals.
Source: AZ Pulmicort Respules Direct Sales (AZ0466414).

C. THE FLAWS IN DR. HARTMAN'S DAMAGES METHODOLOGY ARE CLEAR FROM PULMICORT RESPULES EXPERIENCE

66. In analyzing liability and damages, Dr. Hartman treats all drugs that qualify for reimbursement under Medicare Part B in the same way for purposes of his analysis. This means that he completely ignores any differences in the competitive factors that affect the list price and discounting for particular drugs. Yet, a comparison of the history of Zoladex and Pulmicort Respules shows the importance of understanding the individual competitive environment for each

drug in evaluating a manufacturer's decision on how to set WAC and on the appropriate level of discounting.

67. Dr. Hartman's formulaic approach results in his claiming Pulmicort Respules damages in 2000 and 2001 (in his Addendum), even though no J-code had been assigned. This clearly is an artifact of applying a common methodology to products without considering the drug-specific, idiosyncratic factors that affect marketing strategies. In this case, Dr. Hartman assumes that 10 percent of Pulmicort Respules are reimbursed through Medicare Part B each year from 2000 to 2004, even though he lacks any data with which to make this determination and he has ignored real-world evidence (and deposition testimony) that contradicts his assumption. Given the absence of a J-code, clearly there can be no liability or damages in 2000 and 2001.

68. In his analysis, Dr. Hartman also ignores the implications of the price history of Pulmicort Respules before it was assigned a J-code. The "incentives" for the AWP fraud that Dr. Hartman claims occurred resulted from manufacturers' desire to increase their share, given how Medicare reimbursed for Part B drugs. Even Dr. Hartman would have to acknowledge that these incentives did not exist in 2000 and 2001, when no J-code was assigned. Yet, experience in 2002 and beyond demonstrates, contrary to Dr. Hartman's claims, that nothing changed despite the assignment of a J-code. The spread was unchanged, the rate at which WAC (and AWP increased) was moderate, and ASP increased in line with WAC.

69. Finally, Dr. Hartman calculates damages for Pulmicort Respules only in his Addendum and only because he reduces the "yardstick" spread from 30 percent to

zero. Yet, he has presented considerable evidence in his Initial Report that spreads that he concedes are "non-fraudulent" -- because they are either unaffected by the incentives that he claims lead to fraud or because they are widely known to prevail in the marketplace -- exceed zero. In fact, Dr. Hartman provides evidence that the size of the spread that he calculates for Pulmicort Respules is typical for transactions that he admits are non-fraudulent. His rationale for adopting a yardstick of zero in his Addendum is that Medicare statutes required reimbursement at the lower of ASP (EAC) or the prevailing percentage of AWP, so presumably reimbursement at higher levels occurred only because of manufacturer fraud. But, this presumption cannot apply to Pulmicort Respules, because pricing of the small fraction of sales reimbursed under Medicare B is not determined independently from pricing generally for Pulmicort Respules.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Hon. Patti B. Saris **FILED UNDER SEAL**

DECLARATION OF JAYSON S. DUKES IN SUPPORT OF THE JOHNSON & JOHNSON DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AS TO CLASS 1 AND CLASS 2

percentage of ASP. In this respect, "spread" is expressed as a percentage above ASP, rather than as the percentage below AWP. This is not the only way in which "spread" could be calculated. For example, one alternative way to calculate "spread" would be to express the difference between AWP and ASP as a percentage of AWP. A "spread" that is 20% above ASP (the way Dr. Hartman expressed the percentage) is the same as a "spread" that is 16.7% below AWP (the way many reimbursement contracts express the percentage).

11. Fourth, FTI Consulting was asked to calculate Procrit®'s pricing by class of trade.

12. Fifth, FTI Consulting was asked to calculate the effect of treating Centocor's managed care rebates as a credit against Remicade®'s "spread."

13. Sixth, FTI Consulting was asked to prepare charts showing, by year, and by NDC, all instances where Dr. Hartman and his staff calculated "spreads" for Procrit® that exceed 30%. We prepared separate charts showing these calculations based on both of Dr. Hartman's methodologies.

III. METHODOLOGY

14. It is my understanding that the sales, chargeback and rebate data supplied to FTI Consulting was the same as that supplied to Dr. Hartman and his staff. A list of the documents reviewed by FTI employees is annexed to this Declaration as Attachment 3.

15. In calculating the Procrit® and Remicade® ASPs and "spreads" we adopted and applied the two methodologies described in Dr. Hartman's Reports dated December 15, 2005 and February 3, 2006.

A. Dr. Hartman's December 15, 2005 Methodology

16. Dr. Hartman's December 15, 2005 Report describes his initial method of calculating ASP as follows (¶ 61):

> I integrate all sales, chargeback and rebate data for all physician-administered and Medicare Part B covered drugs ....
>
> Broadly speaking, I use the identifiers for customer name, type, and class of trade to exclude, at Node A, all direct units sold to such entities as hospitals, government entities, managed care dispensaries, and those units distributed through wholesalers which are not later distributed to the physician providers who in turn administer to the Class.... When I exclude those units distributed to entities who are not providers to Sub-class members, I also exclude the related chargebacks and rebates. As a result, the ASPs I present in Attachment G are based upon invoiced sales data, price offsets, chargebacks and rebates on units distributed solely to the Sub-classes.

17. Using the same methodology described in Dr. Hartman's December 15, 2005 Report, my staff and I calculated ASPs and the associated "spreads" for all units of Procrit® and Remicade® dispensed through all providers other than hospitals, managed care entities, and governmental entities. Listings of the specific transactions we excluded from our calculations are annexed to this Declaration as Exhibits 1 and 2.

18. When my staff and I calculated the ASPs and associated "spreads" in accordance with Dr. Hartman's December 15, 2005 methodology, we observed that Dr. Hartman's staff failed to identify and comprehensively remove from their calculations all of the direct units sold to hospitals, managed care entities, and governmental entities. See ¶ 43, *infra*.

19. Consequently, the ASP and "spreads" in Dr. Hartman's December 15, 2005 Report do not accurately conform to his intended methodology.

B. Dr. Hartman's February 3, 2006 Methodology

20. Dr. Hartman's February 3, 2006 Report describes an alternate method of calculating ASP as follows (¶ 2):

> One manner to calculate the spread is that the AWP, and the ASP for which it is a signal, should summarize **all** non-governmental, non-*de minimus* transactions, rather than the subset included in my earlier analysis. Using this analysis, I have therefore recalculated the ASPs for all NDCs of all relevant drugs for all units dispensed through all providers other than governmental providers.

21. Dr. Hartman's February 3, 2006 methodology differs from his first methodology in that units sold to hospitals and managed care dispensaries are included in the ASP and "spread" calculations. The only sales that Dr. Hartman intended to exclude from his second set of calculations were units sold to governmental entities.

22. Using the same methodology described in Dr. Hartman's February 3, 2006 Report, my staff and I calculated ASPs and the associated "spreads" for all units of Procrit® and Remicade® dispensed through all providers excluding only governmental entities.

23. When my staff and I calculated the ASPs and associated "spreads" in accordance with Dr. Hartman's February 3, 2006 methodology, we observed that Dr. Hartman's staff failed to identify and comprehensively remove from their calculations all of the direct units sold to governmental entities. See ¶ 43, *infra*.

24. Consequently, the ASP and "spreads" in Dr. Hartman's February 3, 2006 Report do not accurately conform to his intended methodology.

IV. CALCULATIONS OF THE PROCRIT® AND REMICADE® ASPS AND ASSOCIATED "SPREADS" AS PER THE METHODOLOGY DESCRIBED IN DR. HARTMAN'S DECEMBER 15, 2005 REPORT

A. Dr. Hartman's Calculations as per the Methodology Described in Dr. Hartman's December 15, 2005 Report

25. Dr. Hartman's December 15, 2005 calculations of the Procrit® and Remicade® ASPs were attached to his December 15, 2005 Report as Attachment G.4.a. A copy of that Attachment is annexed to this Declaration as Exhibit 3.

26. Dr. Hartman's December 15, 2005 calculations of the Procrit® and Remicade® "spreads" were attached to his December 15, 2005 Report as Attachment G.4.c. A copy of that Attachment is annexed to this Declaration as Exhibit 4.

27. Dr. Hartman's December 15, 2005 calculations of Procrit®'s ASPs, by NDC, and by year, yielded 116 separate "spread" calculations. He identifies 97 Procrit "spreads" that were less than 30% (84%), three Procrit® "spreads" that were equal to 30% (3%), and 16 Procrit® "spreads" that exceeded 30% (14%).[1]

28. Dr. Hartman's December 15, 2005 calculations of Remicade®'s ASPs, by NDC, and by year, yield six "spread" calculations, all of which exceed 30%. He finds that Remicade®'s "spread"'s were 30.8% in 1998, 33.4% in 1999, 31.9% in 2000, 36.1% in 2001, 33.9% in 2002, and 34.3% in 2003.

B. FTI Consulting's Calculations as per the Methodology Described in Dr. Hartman's December 15, 2005 Report

29. When my staff and I applied the methodology described in Dr. Hartman's December 15, 2005 Report, excluding the hospital, managed care, and government transactions identified in Exhibit 1, we found that the ASPs for Procrit® are frequently higher than those listed in Attachment G.4.a of Dr. Hartman's Report. Our calculations of Procrit®'s ASPs, by NDC, and by year, are shown in the table annexed to this Declaration as Exhibit 5.

30. When my staff and I applied the methodology described in Dr. Hartman's December 15, 2005 Report, excluding the hospital, managed care, and government transactions identified in Exhibit 1, we found only one Procrit® "spread," for one Procrit® NDC, for one year, that exceeded 30%, and I suspect that that one figure may reflect data anomalies, which I am continuing to investigate. Our calculations of Procrit®'s

[1] In his December 15, 2005 Report, Dr. Hartman's calculated three Procrit® "spreads" that allegedly exceeded 50%, including one NDC in 1993 that was 221.3%. In my opinion, based upon my own calculations, these three "spread" calculations (and others) are incorrect. I note that Dr. Hartman's second set of calculations, discussed below, do not show any NDCs with "spreads" above 50%, and only one NDC with a "spread" above 40%. (The 221.3% "spread" is reduced to 35.3%.) I interpret Dr. Hartman's revisions to suggest that he agrees with me that his initial calculations showing three Procrit® "spreads" in excess of 50% were incorrect.

"spreads," by NDC, and by year, are shown in the table annexed to this Declaration as Exhibit 6.

31. When my staff and I applied the methodology described in Dr. Hartman's December 15, 2005 Report, excluding the hospital, managed care, and government transactions identified in Exhibit 2, we found that Remicade®'s ASPs were invariably higher than those listed in Attachment G.4.a of Dr. Hartman's Report. Our calculations of Remicade®'s ASPs, by NDC, and by year, are shown in the table annexed to this Declaration as Exhibit 5.

32. When my staff and I applied the methodology described in Dr. Hartman's December 15, 2005 Report, excluding the hospital, managed care, and government transactions identified in Exhibit 2, we found that none of the Remicade® "spreads" exceeded 30%. Our calculations of Remicade®'s "spreads," by NDC, and by year, are shown in the table annexed to this Declaration as Exhibit 6.

33. A chart comparing Dr. Hartman's calculations and FTI Consulting's calculations, both performed according to the methodology described in Dr. Hartman's December 15, 2005 Report is annexed to this Declaration as Exhibit 7.

V. CALCULATIONS OF THE PROCRIT® AND REMICADE® ASPS AND ASSOCIATED "SPREADS" AS PER THE METHODOLOGY DESCRIBED IN DR. HARTMAN'S FEBRUARY 3, 2006 REPORT

A. Dr. Hartman's Calculations as per the Methodology Described in Dr. Hartman's February 3, 2006 Report

34. Dr. Hartman's February 3, 2006 calculations of the Procrit® and Remicade® ASPs were attached to his February 3, 2006 Report as Attachment G.4.a. A copy of that Attachment is annexed to this Declaration as Exhibit 8.

35. Dr. Hartman's February 3, 2006 calculations of the Procrit® and Remicade® "spreads" were attached to his February 3, 2006 Report as Attachment G.4.c. A copy of that Attachment is annexed to this Declaration as Exhibit 9.

36. Dr. Hartman's February 3, 2006 calculations of Procrit®'s ASPs, by NDC, and by year, yielded 116 separate "spread" calculations. He identified 97 Procrit "spreads" that were less than 30% (84%) and 19 Procrit® "spreads" that exceeded 30% (16%).

37. Dr. Hartman's February 3, 2006 calculations of Remicade® ASPs, by NDC, and by year, yielded six "spread" calculations, five of which exceed 30%. He found that Remicade®'s "spread" was 30.7% in 1998, 34.8% in 1999, 29.4% in 2000, 36.1% in 2001, 33.9% in 2002, and 34.3% in 2003.

B. FTI Consulting's Calculations as per the Methodology Described in Dr. Hartman's February 3, 2006 Report

38. When my staff and I applied the methodology described in Dr. Hartman's February 3,

2006 Report, excluding the specific transactions identified in Exhibit 2, we found that the ASPs for Procrit® were frequently higher than those listed in Attachment G.4.a of Dr. Hartman's Report. Our calculations of the Procrit® ASPs, by NDC, and by year, are shown in the table annexed to this Declaration as Exhibit 10.

39. When we applied the methodology described in Dr. Hartman's February 3, 2006 Report, excluding the transactions identified in Exhibit 2, we found that only 12 Procrit® "spreads" that exceeded 30%. Our calculations of Procrit®'s "spreads," by NDC, and by year, are shown in the table annexed to this Declaration as Exhibit 11.

40. When my staff and I applied the methodology described in Dr. Hartman's February 3, 2006 Report, excluding the transactions identified in Exhibit 2, we found that Remicade®'s ASPs were typically higher than those listed in Attachment G.4.a of Dr. Hartman's Report. Our calculations of the Remicade® ASPs, by NDC, and by year, are shown in the table annexed to this Declaration as Exhibit 10.

41. When my staff and I applied the methodology described in Dr. Hartman's February 3, 2006 Report, excluding the transactions identified in Exhibit 2, we found that three of the Remicade® "spreads" exceeded 30%. Our calculations of Remicade®'s "spreads," by NDC, and by year, are shown in the table annexed to this Declaration as Exhibit 11.

42. A chart comparing Dr. Hartman's calculations and FTI Consulting's calculations, both performed according to the methodology described in Dr. Hartman's February 3, 2006 Report is annexed to this Declaration as Exhibit 12.

VI. DR. HARTMAN AND HIS STAFF FAILED TO ACCURATELY CALCULATE THE PROCRIT® AND REMICADE® ASPS AND ASSOCIATED "SPREADS" AS PER THE METHODOLOGIES DESCRIBED IN DR. HARTMAN'S DECEMBER 15, 2005 AND FEBRUARY 3, 2006 REPORTS

43. In order to accurately calculate the Procrit® and Remicade® ASPs and associated "spreads" as per the methodology described in Dr. Harman's December 15, 2005 Report, Dr. Hartman and his staff were required to identify and exclude from their calculations "all direct units sold to such entities as hospitals, government entities, managed care dispensaries, and those units distributed through wholesalers which are not later distributed to the physician providers who in turn administer to the Class."

44. In order to accurately calculate the Procrit® and Remicade® ASPs and associated "spreads" as per the methodology described in Dr. Harman's February 3, 2006 Report, Dr. Hartman and his staff were required to identify and exclude from their calculations all direct units sold to government entities.

45. The failure to identify and exclude the direct units sold to the entities identified for exclusion under either of Dr. Hartman's two methodologies will result in inaccurate ASP and "spread" calculations. Because the prices charged to hospitals, managed care dispensaries, and the government are typically lower than the prices charged to other classes of trade, the failure to exclude sales made to these entities can be expected to

result in lower ASPs, and larger "spreads."

46. There are compelling reasons to conclude that Dr. Hartman's staff failed to identify and exclude all of the direct units sold to the entities identified for exclusion under Dr. Hartman's two methodologies, and that this failure explains, in part, why the ASPs and associated "spreads" that Dr. Hartman's staff calculated under his direction differ from the ASPs and associated "spreads" calculated by FTI Consulting.

47. It is understandable, and not surprising, that Dr. Hartman's staff were unable to identify and exclude all of the transactions that Dr. Hartman intended for them to exclude. The multiple data sets produced by the Johnson & Johnson Defendants contain over four million transactions. The chargeback and rebate data, and the associated class of trade designations, were sometimes difficult to interpret and apply. My staff and I posed numerous data-related questions to Johnson & Johnson's counsel and to knowledgeable individuals at various Johnson & Johnson operating companies. Their responses enabled us to resolve numerous issues that were otherwise indeterminate. Dr. Hartman's staff presumably encountered many of the same issues, but had to resolve them without having commensurate access to company personnel.

48. Neither of the Reports submitted by Dr. Hartman includes a comprehensive listing of all of the transactions that his staff excluded from their calculations. Nevertheless, it is clear that Dr. Hartman's staff excluded fewer transactions than we did. A comprehensive listing of the sales transactions we excluded from our calculations are provided as Exhibits 1 and 2 to this Declaration.

49. My conclusion that Dr. Hartman's staff did not exclude all of the transactions that Dr. Hartman intended for them to exclude is based on the following facts. First, I provide as Exhibit 13 to this Declaration a comparison of the total number of chargeback units Dr. Hartman excluded from his February 3, 2006 ASP calculations by NDC and by year to the total number of chargeback units I exclude by NDC and by year. For years 1991 through 1999, in a majority of the instances, the number of chargeback units that I excluded is higher than the number of chargeback units that Dr. Hartman excluded. Second, I have included as Exhibits 14 and 15 a listing of Procrit® and Remicade® government transactions we believe Dr. Hartman failed to exclude from his calculation. We compiled these lists by identifying specific government transactions assigned to certain COT codes Dr. Hartman said he did not exclude from his ASP calculations. Dr. Hartman primarily identified transactions to exclude based upon COT codes.

50. Because the calculations performed by Dr. Hartman and his staff did not exclude all of the hospital, managed care, and/or government transactions that Dr. Hartman intended to exclude, the calculations of the Procrit® and Remicade® ASPs and "spreads" set forth in Dr. Hartman's December 15, 2005 Report did not accurately reflect his intended methodology.

51. Because the calculations performed by Dr. Hartman and his staff did not exclude all of the government transactions that Dr. Hartman intended to exclude, the calculations of

the Procrit® and Remicade® ASPs and "spreads" set forth in Dr. Hartman's February 3, 2006 Report did not accurately reflect his intended methodology.

52. Dr. Hartman's ASP and "spread" calculations for Remicade® are inaccurate because his calculations erroneously includes fees that Centocor paid to specialty distributors for data, call support, and other services. I am advised that these service fees reflect value received and that the specialty distributors were under no obligation to share these fees with their customers in the form of lower prices. Consequently, these fees should neither be viewed as reductions in Remicade®'s purchase price, nor included in the calculation of Remicade®'s ASPs.

VII. OTHER ANALYSES

A. Procrit® Price Point Analysis By Class of Trade

53. I calculated Procrit®'s selling prices for each of the following classes of trade: (1) government, (2) managed care entities, (3) non-government hospitals, (4) non-government long term care and home health facilities, (5) non-government physician/clinics, and (6) retail pharmacies. This analysis shows that retail pharmacies typically paid higher prices for Procrit® than other classes of trade, and that managed care, government, and hospitals obtain the most favorable prices. My class of trade analysis is annexed to this Declaration as Exhibit 16.[2]

B. Remicade® Managed Care Analysis

54. Managed care entities pay for Remicade®. The rebates they receive from Centocor have the effect of lowering their net reimbursement costs. Dr. Hartman purports to exclude managed care transactions from the calculations set forth in his December 15, 2005 Report, which means they have no effect on his ASP or "spread" calculations. He included managed care rebates in the ASP calculations set forth in his February 3, 2006 Report, which has the effect of lowing the ASP and increasing the "spread."

55. Because managed care entities pay for Remicade®, they *benefit* from the rebates they receive. Ignoring these benefits in the calculation of ASP fails to credit the manufacturer for reducing reimbursement costs, whereas including them in the calculation of ASP punishes the manufacturer for reducing reimbursement costs.

56. Accordingly, I have recalculated the "spreads" for Remicade® treating managed care rebates as a credit against the "spread." The recalculated "spreads" for 2001 through 2003 would be 29.94%, 29.43% and 28.40% respectively.

C. "Pattern" Analysis

57. In order to test the assertion that Procrit®'s "spreads" reflect a "pattern" of

[2] For 2003, for the retail class of trade, returns for certain of the discount levels were higher than the sales for the same discount levels. This timing issue has caused negative percentages for certain of the discount levels and a percentage greater than 100% in others.

manipulating the spread, I was asked to create charts showing the instances, by year, and by NDC, where Dr. Hartman identified Procrit® "spreads" in excess of 30%.

58. A chart identifying Procrit® "spreads" greater than 30%, as calculated by Dr. Hartman and his staff pursuant to the methodology described in his December 15, 2005 Report, is annexed to this Declaration as Exhibit 17.

59. A chart identifying Procrit® "spreads" greater than 30%, as calculated by Dr. Hartman and his staff pursuant to the methodology described in his February 3, 2006 Report, is annexed to this Declaration as Exhibit 18.

60. I am advised that Dr. Hartman has testified that, in his opinion, one indicia of whether a manufacturer is illegally manipulating a product's AWP is the "pattern" of its "spread" over time. As shown in Exhibits 17 and 18, the Procrit® "spreads" calculated by Dr. Hartman's staff do not appear to form any discernable pattern.

61. According to Dr. Hartman's December 15, 2005 Report, the "spread" on some NDCs did not exceed 30% in any of the years they were sold, whereas the "spread" on other NDCs exceeded it only once or twice. Only two NDC "spreads" allegedly exceeded 30% three times, and even those two NDCs usually did not exceed 30%.

62. There is also no discernable pattern as to when Procrit®'s NDCs allegedly exceeded 30% and when they did not. In 1991, 1992, 1994, 2000, and 2001, none of Procrit®'s "spreads" exceeded 30%. In 1993, two out of 11 NDCs had "spreads" that allegedly exceeded 30%. In 1995, only one "spread" on one NDC allegedly exceeded 30% (by 0.3%), but that NDC's "spread" was less than 30% in all other years between 1991 and 2003.

63. This Declaration is based on documents reviewed and analyses performed to date. If additional information is provided to me subsequent to the execution of this Declaration, I reserve the right to modify or change this Declaration.

I declare under penalty of perjury that this Declaration is true and correct.

Executed on March 15, 2006

3/15/06

Jayson S. Dukes

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-12257-PBS
	Judge Patti B. Saris
THIS DOCUMENT RELATES TO: ALL CLASS ACTIONS	[FILED UNDER SEAL PURSUANT TO COURT ORDER]

DECLARATION OF SUMANTH ADDANKI, PH.D.

March 15, 2006

threshold spread of 30 percent of "ASP", i.e., that an AWP that was more than 30 percent above "ASP" was artificially inflated.[7]

19. Using the results of these tests for liability, Dr. Hartman, then purports to calculate "class-wide damages" for each of the three classes. He does this by calculating his estimated overcharge for each accused drug based on the threshold value noted above, and then multiplying that overcharge by the volume of each accused drug that he asserts was sold into the channel represented by each of the classes certified by the Court.[8]

III. Analysis of Liability and Causation Thresholds for Classes 1 and 2

A. The Assumption of Equality of "ASP" and AWP Is Fatally Flawed

20. The plaintiffs assert that, as a matter of statute, AWP necessarily should have equaled "ASP".[9] As a matter of economics, this is absurd. Quite apart from the reasons why this makes no sense in the specific context of pharmaceuticals, it is simply wrong-headed at the most general level. The AWP, according to the plaintiffs, is meant to represent the average ***wholesale*** price, the price ***received*** by wholesalers. Why this should equal the price received by manufacturers, i.e., ***paid by*** wholesalers, is entirely a mystery, unless the plaintiffs are urging that wholesalers should sell product for exactly the price at which they bought it. As

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[7] See, e.g., "Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calcu[l]ation of Damages," December 15, 2005, p. 40, ("[I]f a manufacturer either raises its AWP and/or lowers its ASP such that the realized spread exceeds 30% for a given NDC for a given period of time (I choose a year), I conclude that the manufacturer has fraudulently increased the spread on that NDC in that period to move market share.")

[8] See, e.g., "Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calcu[l]ation of Damages," December 15, 2005, p. 6, ("I use these spreads to calculate aggregate damages on the units reimbursed by the three Sub-Classes for the drugs of each of the five Track One Defendants.") See also "Supplemental Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages: Addendum," February 3, 2006, p. 1.

[9] See, e.g., "Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calcu[l]ation of Damages," December 15, 2005, p. 13, ("[B]y statute the but-for spread for those single-source brand-name drugs reimbursed by Sub-Classes 1 and 2 was 0.0%.") See also p. 14, ("[A]s with single-source brand-name drugs, the ASP [for multi-source drugs] was the 'but-for AWP' for 1991-2003, and the 'but-for spread' was 0.0%.")

an economic proposition, this makes no sense, and the plaintiffs certainly offer no reason whatsoever why wholesalers should be expected to sell all of their product at zero markups (i.e., assuring that they will operate at a loss).

21. To see this in the specific case of pharmaceuticals, let us note, to begin with, that there is only one AWP for any given NDC. Therefore, *any* reimbursement scheme that is tied to AWP (and, as the plaintiffs themselves note, that includes the majority of reimbursement formulae) depends upon that one AWP.[10] Note, further, that *many* reimbursement schemes pay providers and pharmacies an amount *less than* AWP. Indeed, other government programs themselves, such as Medicaid, reimburse at rates below the AWP.[11]

22. The implications are immediate: if the "ASP" is what the *manufacturer* obtains for *its* sale of a given NDC, unless the remainder of the distribution chain is willing to suffer a loss *on every single unit that it sells* of that NDC, the AWP—only some fraction of which will be paid as reimbursement when the drug is dispensed—cannot possibly be as low as the "ASP". For example, if we know that the manufacturer's "ASP" for a unit sold is $2.00, the AWP cannot possibly equal $2.00, because if it did, and reimbursement is, say, at 90 percent of AWP, or $1.80, the rest of the distribution chain—wholesaler, distributor, pharmacy/provider—would have to absorb a loss on every unit sold! No rational economic agent would even carry the product under these circumstances.

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[10] See, e.g., "Average Wholesale Price Litigation Liability Report of Dr. Meredith Rosenthal," December 15, 2005, p. 11.

[11] See, e.g., "Variation in State Medicaid Drug Prices," Office of the Inspector General, U.S. Department of Health and Human Services, September 2004, OEI-05-02-00681, p. 2 ("In general, States reimburse pharmacies for drugs at the lower of: (1) estimated [pharmacy] acquisition cost; or (2) the pharmacy's usual and customary charge to the general public. ... Estimating pharmacy acquisition cost can present a challenge for States. Most often, States rely on published prices, including average wholesale price (AWP) and wholesaler acquisition cost ...However, numerous studies and audits by the Office of Inspector General (OIG) and other experts have found that these list prices, particularly AWP, overstate the prices pharmacies pay. For this reason, CMS requires that States using AWP include a significant discount off this price for CMS to consider it an acceptable estimate of pharmacy acquisition cost.").

23. Certainly, the "ASP" is an *average* selling price, and some units would be sold for less than the "ASP" while others would be sold for prices higher than the "ASP". But this does nothing to resuscitate the equality assumption proposed by the plaintiffs, because, again, every player in the distribution chain that paid *more* than the "ASP" would suffer even greater losses, while players paying less than the "ASP" (but more than $1.80) would still be losing money on every unit. Again, most players would not even carry the product under these circumstances.

24. The problem is that the equality assumption that the plaintiffs propose is incompatible with the basic economic incentives that are required for products even to be distributed and is, therefore, unusable. Neither the plaintiffs nor their experts seem to have considered the absurd conclusions to which this assumption necessarily drives us.

B. The Assumption of Equality of AWP and "ASP" Leads to Absurd Results that Contradict the Plaintiffs' Own Assertions

25. Perhaps even more important, if one were, in fact, to impose the requirement that AWP equal "ASP", no pharmaceutical product on the market would pass the test for liability that this requirement logically implies. Most drugs sold in the market are sold at transaction prices that, on average, are substantially below AWP—at least 20 to 25 percent less than AWP for branded drugs with substantially greater discounts for generics, in fact. Therefore, by the plaintiffs' assumption of equality, nearly every single NDC of every single pharmaceutical product on the market would be liable. Not only is this patently absurd, it flatly contradicts other of the plaintiffs' own assertions. The plaintiffs themselves have noted that of the thousands of NDCs on the market, only the handful identified and accused here are subject to the alleged manipulation scheme.[12] As

[12] See, e.g., "Written Tutorial of Meredith Rosenthal, Ph.D.," pp. 2-3, ("There are approximately 65,000 different prescription drugs in the United States market. The use of AWP as a pricing mechanism for the vast majority of these drugs is not at issue in the AMCC or in this motion. The plaintiffs instead claim that with respect to 132 of the drugs manufactured by the five fast track defendants (a subset of all drugs manufactured by these (continued...)

a simple matter of economics and logic, the plaintiffs' assumption leads to a test that cannot discriminate those products that were subject to the alleged scheme from those that were not but, rather, simply declares that all products were liable. The assumption of equality cannot be valid under these circumstances and must be set aside.

26. Finally, the plaintiffs' position that AWP would equal ASP is directly contradicted by Dr. Hartman's own assumptions for Class 3. Again, recall that a given NDC only has one single AWP, and the ASP is a single number as well: the average price received by the manufacturer on its sales of that NDC. The AWP cannot be equal to the ASP for purposes of Classes 1 and 2 and, simultaneously, 30 percent above the ASP for purposes of Class 3! Once again, the plaintiffs and their experts appear not to have considered the logical inconsistency between and among the assumptions that they have made. At the very least, the plaintiffs' assumption with regard to the "but-for spread" for Classes 1 and 2 should comport with the assumptions used for Class 3. Unfortunately, the "analysis," assumptions and conclusions regarding the Class 3 accused drugs—Schering's and Warrick's accused drugs in particular—are equally ill-conceived and unsupportable, as I will demonstrate below in Section V.

(...continued)

companies), the use of AWP as an industry standard was exploited by defendants..." (footnotes not reproduced)).

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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris Chief Magistrate Judge Marianne B. Bowler

DECLARATION OF DANIEL L. MCFADDEN

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MARCH 21, 2006

or are unaware that the introduction of competition among products generally leads to lower prices, and have no information channels or mechanisms to obtain ASPs. Therefore, under those circumstances, the failure of insurers to look after their own interests is explained entirely by the fact that drug companies do not make ASPs public or ensure that published AWPs track ASPs by a "reasonably predictable amount."

41. These assumptions and conclusions can be tested both through standard principles of economic theory and empirically. If any of these assumptions is incorrect, Dr. Hartman's conclusions also will be incorrect.

IV. DR. HARTMAN'S ANALYSIS DOES NOT MEET A SCIENTIFIC STANDARD

42. In the sections that follow, I show that Dr. Hartman's analysis and conclusions regarding liability and damages are implausible. Here, I examine the approach followed by Dr. Hartman to test the critical hypotheses and assumptions that underlie his conclusions and to contrast his approach with standard scientific methods. I show that despite claims of performing science, Dr. Hartman repeatedly follows an incorrect scientific approach.[20]

43. The economics profession, to the extent it is applying scientific methods to a problem, generally proceeds in four basic steps:

i. Specifying a clear model or hypothesis to be evaluated or tested, including identification of critical assumptions;

ii. Collecting reliable data and information;

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[20] Dr. Hartman testified: "Yeah, fair is – I'm not being asked to be fair here, I'm being asked to be – to do science . I'm going to ask that to the extent that it's scientifically sensible and can be ascertained via a survey about how their expectations were informed relative to the data that I see in the industry." Hartman Deposition, October 8, 2004, p. 229.

iii. Analyzing the model or hypothesis using data, including calibrating the model, estimating unknown parameters, and testing of hypotheses; and

iv. Reaching reliable conclusions, forecasts, findings, predictions, and inferences based on the previous steps.

44. Dr. Hartman's analysis in effect assumes his conclusion about the existence of the alleged fraud. This is most easily seen by working backwards in a series of steps from the damage calculation:

i. Dr. Hartman argues that actual spreads in excess of the but-for yardstick of 30% constitute evidence of liability for fraud and damages;[21]

ii. Dr. Hartman argues that plaintiffs held "market expectations" that the relationship between AWP and ASP was "a reasonably predictable" amount;[22]

iii. Dr. Hartman argues that the "reasonably predictable amount" can be estimated by assuming that class members accurately held "market expectations" that a common "yardstick" of 30% applies as a conservative upper limit to expected spreads for all NDCs and time periods in the but-for world;[23]

iv. Dr. Hartman argues that all NDCs, class members, and time periods are expected to share a common expected "yardstick" in the but-for world because "lack of pricing transparency" (*i.e.*, little or no data) on either actual or expected spreads means there is no reason to assume otherwise;[24] and

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[21] Hartman Declaration, December 15, 2005, p. 40.

[22] Hartman Declaration, September 3, 2004, p. 7.

[23] Hartman Declaration, December 15, 2005, p. 40.

[24] Hartman Declaration, December 15, 2005, p. 42.

v. Dr. Hartman argues that four sources of information (later reduced to three) can be reliably used to infer that plaintiffs' "market expectations" are based on a "yardstick" threshold of 30%.[25]

45. If the theory or empirical support for any of these steps is unreliable, the damage calculation will be unreliable because each step in the chain of argument is needed to reach the conclusion.

46. Dr. Hartman's damage methodology misapplies basic principles of hypothesis testing in economics. Science requires providing convincing evidence that a critical hypothesis should be accepted. The appropriate test is whether alternative explanations can be rejected as unlikely or impossible because they conflict with compelling evidence. Dr. Hartman does not undertake such an approach and often accepts his hypothesis without consideration of alternatives that explain his data or based on an inability to find appropriate data with which to test it.

47. In the absence of compelling data, Dr. Hartman's approach can be used to confirm many conflicting hypotheses, however implausible. Using this approach, weak or nonexistent data will mean that either a hypothesis or its antithesis will be accepted depending on which is arbitrarily accepted as the candidate hypothesis. To prevent this, the economically correct approach is as follows:

- Pose a candidate hypothesis that something is true; and then
- Accept the candidate hypothesis with confidence only if strong evidence rules out (*i.e.*, rejects) the antithetical or contrary hypothesis with confidence.

48. The Hartman approach tips the scales in favor of accepting his central hypothesis of a common yardstick for all class members, NDCs and time periods for the but-for world in the absence of convincing data, because it accepts the hypothesis unless it can be convincingly disproved. To the extent that Dr. Hartman's evidence is inconclusive or irrelevant, however,

[25] Hartman Declaration, December 15, 2005, pp. 14-17.

it should have caused him to reject the hypothesis of a common yardstick as implausible. Moreover, to the extent that the evidence in the Hartman Report is relevant, it actually supports rejecting the hypothesis and accepting the alternative that there is no common yardstick that can be calculated reliably. Dr. Hartman's analysis therefore is fundamentally flawed. Dr. Hartman makes the same basic error in hypothesis testing when evaluating the data sources he uses to establish his 30% estimate of the yardstick. I comment briefly on the methodology used by Dr. Hartman to test each of the critical assumptions of his methodology.

49. **Dr. Hartman's Assumption: Any evidence of actual spreads in excess of the but-for yardstick of 30% can only be explained by fraud.**

Dr. Hartman makes no investigation of whether this assumption is theoretically or empirically true. I explain in this report why competition is a critical factor that did and would be expected to explain spreads in excess of 30%. Dr. Hartman also fails to test this assumption against direct evidence that payors either knew of spreads in excess of the 30% yardstick or "simply did not care," thereby contradicting his expectations theory of liability. Nor did he analyze how changes in expectations about spreads would be expected to change reimbursement rates or examine evidence that reimbursement rates already reflect knowledge of spreads during the damage period.

50. **Dr. Hartman's Assumption: Class members believed that there was a spread between AWP and ASP and they expected that the relationship between AWP and ASP was governed by a "reasonably predictable amount" which is empirically estimable.**

The appropriate scientific test would be to develop data on the expectations of class members to determine if the alternative hypothesis – that no such expectation existed – could be ruled out. Dr. Hartman indicated in the earlier phases of this proceeding that he would

survey expectations.[26] No such test was conducted and no data regarding whether class members generally had expectations about the level of spreads, and if so what they were, were introduced. As I have discussed above, there exists evidence that many payors did not have this expectation and that several public surveys which Dr. Hartman suggested reflect and inform expectations show clearly that spreads increase as competition increases.

51. **Dr. Hartman's Assumption: The same 30% yardstick applies to all class members.**

Dr. Hartman assumes that the same 30% yardstick applies to all class members, because he believes that there are no data to justify otherwise: "There is no reason to assume that 'each TPP had a different level of knowledge regarding the spread ...."[27] This is another example of Dr. Hartman's accepting a hypothesis because he believes there are no data to refute it. However, on numerous occasions, he states that there were in fact differences in payor knowledge of spreads.[28]

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[26] For Example, Hartman Deposition at 223: 8-18 and at 229: 5-19.

[27] Hartman Declaration, December 15, 2005, p. 9.

[28] Hartman Deposition at 687:19-20: "Well expectations in the market vary. I mean there is a distribution of expectations. At 724:3-6, Dr. Hartman characterizes those who "don't care what acquisition cost is" as follows: these are people, you know, wailing in the wilderness.

52. **Dr. Hartman's Assumption: Class members believed that the maximum spread of 30% would not be exceeded by any NDC covered in any calendar year.**

This assumption implies that class members believed that the ratio of AWP to ASP was at all times less than 1.3 for every NDC over a period of one calendar year. Dr. Hartman does not conduct any tests to validate the view that payors formed expectations at the NDC level and that these expectations were updated each calendar year. He simply assumes that, for example, if a drug had average spreads less than 30% over a two-year average but exceeded 30% in one year, this would violate payor expectations. This is especially curious because Dr. Hartman argues that information disseminates slowly and implies that payor expectations formed more than a decade ago persist today even in the face of new public information.[29]

53. **Dr. Hartman's Assumption: Class members expected that the maximum spread of 30% did not change over time.**

Dr. Hartman finds evidence of increasing awareness by the class members that spreads were increasing over time.[30] However, damages are based on the same 30% yardstick in every period. The justification is not that class members did not change their expectations because they were unaware of the increased spreads over time, but that they did not act on the new information.[31] As I explain below, if lags explain the inability of his expectations model to predict reimbursement rates, then reimbursement rates will not be accurate indicators of expectations (as Dr. Hartman assumes). Moreover, if TPPs' reimbursement rates do not reflect current expectations and do not change in the period studied by Dr. Hartman, Dr. Hartman lacks objective evidence to prove his theory of expectations and revealed

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[29] See for example Hartman Declaration, December 15, 2005, p. 20 and p. 42 and Hartman Deposition, October 8, 2004 at pp. 202-203. It seems implausible to assume, as Dr. Hartman does, that if they had the data, class members would test annually at the detailed NDC level to see whether their expectations had been violated, yet wait years before taking any action on any new information.

[30] Hartman Deposition at 732:10-733:8.

[31] Hartman Deposition at 765:15-766:9.

preferences, because revised expectations about spreads in response to new evidence have yet to be revealed.[32]

54. **Dr. Hartman's Assumption: In the absence of a direct measure of class members' expectations, three surrogate sources can be reliably used to infer that the "reasonably predictable" spread is not more than 30% for any single-source PAD not facing therapeutic competition.**

Dr. Hartman relies here on three comparator drugs,[33] OIG and ASCO surveys, and contracts between physicians and payors to support his assumption that expectations for spreads could not exceed 30%. None of the data sources reveals expectations. There is no evidence offered that the payors formed their expectations based on these data, some of which are not public. The data sources that were public show clearly that some drugs had spreads well in excess of 30% and that spreads increased with competition.

Dr. Hartman also ignores or failed to identify other public studies that also should have led him to reject his hypothesis. For example, one of the products at issue in this case -- Albuterol -- is the subject of six OIG reports, all of them showing spreads far in excess of 30%.[34]

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[32] Dr. Hartman states at 851:5-8, 20-22: "I am seeing it is the same – they are revealing the same kind of contractual reimbursement rates that were reflective of 10 years before that ... all I am saying is that I don't see – and here *they have decided not to do it* [revise reimbursement rates]. *Now maybe no one will decide to do it.*" Emphasis added.

[33] In Table 3 of his Declaration of December 15, 2005, Dr. Hartman provides a list of "drugs of interest." At p. 39, however, he indicates that he analyzed data on spreads for only Zofran, Taxol, and Blenoxane.

[34] See Office of Inspector General Reports: *"Excessive Medicare Reimbursement for Albuterol,"* March 2002, OEI-03-01-00410, *"A Comparison of Albuterol Sulfate Prices."* June 1996, OEI-03-94-00392, *"Update: Excessive Medicare Reimbursement for Albuterol,"* January 2004, OEI-03-03-00510, *"Suppliers' Acquisition Costs for Albuterol Sulfate,"* June 1996, OEI-03-94-00393, *"Are Medicare Allowances for Albuterol Sulfate Reasonable?,"* August 1998, OEI-03-97-00292, and *"Medicare Reimbursement of Albuterol,"* June 2000, OEI-03-00-00311.

55. In the remainder of this report, I show that when Dr. Hartman's assumptions and conclusions are evaluated in light of basic economic theory and in light of undisputed economic incentives faced by physicians, payors, consumers and drug companies, it becomes clear that they are economically implausible.

V. DR. HARTMAN'S LIABILITY ANALYSIS: WAS THERE A MARKET EXPECTATION OF SPREADS AND IF SO WAS IT THAT THE SPREAD ON ANY NDC WOULD NEVER EXCEED 30%?

A. Lack of Direct Evidence on Payor Expectations

56. As a threshold matter, and assuming for the purpose of argument Dr. Hartman's theory of liability, *the correct question is not what was the spread for drugs not facing therapeutic or generic competition.* Rather, the correct question is: *what did payors actually expect spreads to be for those drugs that did face competition - and in particular for the drugs at issue in this case?* The Court appears also to have anticipated that this was what Dr. Hartman would provide, as he acknowledges in his report:

> [Judge Saris] concludes, 'Hartman terms his overall approach the 'yardstick method' because he intends to determine *what the market reasonably expected the spread to be on average* (*e.g.*, AWP is 25% above the average sales price, ASP), and compare this number to the actual spread (*e.g.*, AWP is 100% above ASP) to calculate aggregate Class-wide damages.'[35]

57. Although Dr. Hartman repeatedly testified about how he could develop direct evidence on the expectations of class members, he failed to do so:

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[35] Hartman Declaration, December 15, 2005, p. 14. Emphasis added.

Dr. Hartman:

> ...I'm going to design representative surveys or samples of entities that represent certain parts of the spectrum within the class, within PBMs, within retailers, within mass merchandisers, and perhaps for the manufacturers. I'm going to get claims data that reveals what actually happened, and I'm going to ask that to the extent that it's scientifically sensible and can be ascertained via a survey about *how their expectations were informed relative to the data that I see in the industry*.[36]
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> ***
>
> [L]et's be very clear about class members. What we're going to need is a -- to identify using standard statistical methods a number of selected types of third-party payers and also PBMs and also retailers differentiated in various ways. And we're going to get claims data and *data as to expectation and knowledge for those representative entities* to characterize the class as a whole and the transactions as a whole.[37]
>
> ***
>
> [O]bviously during the damage phase of this, I'm going to have to talk to a lot of Blue Cross Blue Shield administrators and people at Cigna and Aetna and a variety of places.[38]

58. Dr. Hartman's damages and liability report introduces no surveys nor directly cites any deposition evidence[39] showing what were the expectations of the class members. Instead of

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[36] Hartman Deposition at 229:5-19. Emphasis added.

[37] Hartman Deposition at 223:8-18. Emphasis added.

[38] Hartman Deposition at 92:15-20.

[39] At his deposition, 708:16-709:18, Dr. Hartman indicated that he did not explicitly cite any payor deposition in his materials relied upon, but intended to indirectly reference such sources when rebutting Mr. Young's report in his Attachment K of the damage report. See also Hartman Deposition, 705:6-706:6. However, when asked about testimony evidence from payor depositions that appeared to contradict his theory, he argued that the deponents were not suitably experienced or qualified. (See, for example, Hartman Deposition, 749:8-10, 752:18-753:5, 755:1-3, 11-14, where he says: "this ... has no evidentiary value that I see ... this deponent has little credibility as an understanding of what expectations were, relations were, period." At deposition 791:17-21, Dr. Hartman states that even if payors said that they expected spreads greater than 30%, that would not disprove his hypothesis that they did not.)

collecting information "directly from the horse's mouth," as he had planned,[40] Dr. Hartman argues now that class members' self-reported expectations are not reliable.[41,42,43] Thus, Dr. Hartman appears to be claiming that he is more knowledgeable about the expectations of payors than the class members themselves. It also is curious that Dr. Hartman has not presented any data on payors' actual market expectations about spreads, yet he claims that: 1) he can develop reliable estimates of the beliefs of the plaintiffs about spreads and 2) that these beliefs would fall into a small range whose upper limit can be determined and 3) these beliefs applied to every class member, every NDC, and every time period.

59. Instead of showing what plaintiffs' expectations were, Dr. Hartman supports his assumptions using data from three surrogate sources, none of which contains data on the expectations of the class. He uses these sources to estimate what actual spreads have been for single-source innovator drugs not facing competition, leaving untested the propositions that those spreads were understood by class members and that no class member expected that the spread on any drug facing competition exceeded such spreads.[44] A review of each of the data sources, however, shows that if payors relied on this information or that it reveals their expectations, they would in fact expect that spreads on drugs facing therapeutic or generic

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[40] Hartman Deposition at 702:11-705:3.

[41] Hartman Deposition 694:6-7, 702:2-5.

[42] Dr. Hartman argues that the direct testimony of the class members regarding their expectations and about whether they rely on acquisition costs to set reimbursement rates is unreliable. Nevertheless, he appears to rely on information that individuals at payors were "flabbergasted" when they allegedly came to understand the level of spreads in reaching his opinions on liability. See Hartman Deposition at 959:9-960:10.

[43] At deposition transcript 1241:22-1242:12, Dr. Hartman stated that the Cigna representative, who he had previously proposed to rely upon, did not seem to have "a lot of experience in the health care area" and "might be someone who studied it less, is less familiar with the nuances." Similarly, Dr. Rosenthal agrees at numerous places in her deposition: she states that self-reported expectations of payors are unreliable. (See Rosenthal Deposition 138:13-15, 139:2-3, 139:11-15, 141:13-15, 155:12-14, 155:22-156:3.) However, she seems content to rely on her interpretation of documents produced by defendants in discovery: "They corroborate my economic analysis. They look at strategic incentives from the words of the defendants themselves." (Rosenthal Deposition 355:20-22.)

[44] I note that those payors who purchase drugs, such as those with mail order or specialty pharmacies, or with the ability to audit providers could observe spreads directly.

competition would be higher than the spreads on single-source innovator drugs, contrary to his central hypothesis.

B. Comparator Drugs

60. Dr. Hartman's first source of information is data on comparator drugs in periods when they were unaffected by the alleged fraud. He cites NDCs for three such drugs, Zofran, Taxol and Blenoxane[45] and shows that the annual[46] average spreads on these drugs fall within an 18%-27% range during the years in which they did not face any therapeutic or generic competition.[47]

61. Again, there is no evidence offered that the payors formed their expectations based on these three drugs, and the information he examines was confidential and not available to parties outside this litigation.

62. Nonetheless, Dr. Hartman's data for the three drugs shows spreads for both competitive and non-competitive periods. The spreads on the three drugs were significantly higher during periods in which they faced therapeutic or generic competition, as Dr. Hartman acknowledged:

> Dr. Hartman:
>
> The data shows that once Kytril became an active competitor, Glaxo increased their AWP while at the same time decreasing their ASP. This increased their spread and allowed them to effectively market

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[45] Dr. Hartman selectively uses NDCs or averages over NDCs. For example, for Zofran and Blenoxane he chooses a specific NDC, while for Taxol he uses an un-weighted average across all NDC.

[46] The choice of an annual estimation period is arbitrary. ("I choose a year" Hartman Declaration, December 15, 2005, p. 40.) I note that Dr. Hartman does not explain why or how payors updated their expectations on a calendar-year basis. In his initial report, for example, he had indicated that a quarterly analysis could be appropriate. See Hartman Declaration, September 3, 2004.

[47] Hartman Declaration, December 15, 2005, p. 39.

> Zofran to physicians based on the spread which was much higher than their 20% spread prior to Kytril's entry.[48]
>
> ***
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> The data shows that at the time of the first generic, the BMS spread for Blexnoxane increased substantially.[49]

63. Thus, to the extent that actual spreads for these drugs were transparent to payors and informed payor expectations, they indicate payors would have expected higher spreads during periods of competition, and these data refute his central hypothesis regarding expectations. However, if these spreads were not transparent to payors, they could not have informed those expectations or serve as an indicator of what expectations were.

C. Publicly Available Sources

64. A second source of information relied on by Dr. Hartman is publicly available reports that gave information from physician surveys about spreads. Dr. Hartman considers two such reports, the 1992 report of New York State Inspector General (the "OIG survey") and a 2001 report published by the American Society of Clinical Oncologists (ASCO) on Medicare payment reform (the "ASCO report"). As with the comparator drugs, Dr. Hartman offers no evidence that payors relied on these two studies to form their opinions on expected spreads, though he does claim that such documents reflect and inform payor expectations.[50]

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[48] Hartman Declaration, December 15, 2005, Attachment F, p. 4.

[49] Hartman Declaration, December 15, 2005, Attachment F, p. 9.

[50] Dr. Hartman states: "It is reasonable to expect that the findings of these reports form some part of the basis for beliefs about the typical "spread" between AWP and actual acquisition costs of providers (physicians) and retail drug stores." (Hartman Declaration September 3, 2004, Attachment D, p. 9); and "These reports provide preliminary measures of reasonable industry expectations concerning the spread between AWP and ASP for brand-name orals, generic orals and physician administered drugs." (Hartman Declaration September 3, 2004, Attachment D, p. 9) He states also that: "As cited in 22. b) above, in the course of my analysis for this matter I have reviewed a variety of publicly-available survey research *summarizing the "market" expectations of spreads for single-source physician-administered drugs.* (Hartman Declaration December 15, 2005, p. 39.)

1. The OIG Report

65. The OIG survey was limited in scope. It covered thirteen chemotherapy drugs, five New York State physicians, two Medicare carriers and a limited time period (January to July 1991). Spreads were averaged by drug, not by NDC. The OIG study warned:

> This review represents a limited analysis of physicians' costs for 13 chemotherapy drugs. The conclusions reached may not apply in all cases.[51]

66. If the OIG study in fact does reveal payor expectations, then it supports a finding that payors in fact expected spreads for drugs facing therapeutic or generic competition to exceed those for single-source innovator drugs. For example, the 1992 OIG study explicitly states that there is no consistent relationship between AWP and ASP:

> Since the Red Book [the source of AWP used by the two New York State Medicare carriers] does not represent its AWP as a measure of the physician's acquisition cost for drugs, we compared physicians' invoice costs to Red Book's AWP. We found that such costs were not only generally significantly less than AWP, but that there can be a wide variety of AWPs for a given drug depending on the manufacturers and the form of the drug (*e.g.*, solution, powder, lyophilized powder)... Considering that we also found that there is no single discount rate which can be applied to the AWP to provide a reasonable consistent estimate of the physician's acquisition cost, we do not feel that AWP provides a useful measure of the acquisition cost for a drug to physicians.[52]
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> We also found that the relationship between AWP and cost for multiple source drugs varies, depending on large part on the manufacturer" (OIG, p. 5) and that "[O]ne brand name manufacturer

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51 "Physicians' Costs For Chemotherapy Drugs", OIG Study, Appendix II, 1992, p. 11.

52 "Physicians' Costs For Chemotherapy Drugs," OIG Study, Appendix II, 1992. Emphasis added.

> sells this drug (Cyclophosphamide, 500 mg] at 20 percent below AWP while another sells it at 59 percent below AWP.[53]

67. In fact, the OIG study presents much larger spreads. Appendix III of the OIG study shows that invoice costs for PADs (expressed as a percentage below the AWP) differed greatly among drugs. Sales from brand name manufacturers varied from 20% off of AWP to 83% off, while sales from oncology wholesalers varied from 12 to 17% off AWP for one drug to 81 to 82% off AWP for another. An invoice cost of 80% below AWP indicates a spread of 400%. Moreover, the 400% spread comes from a limited sample of drugs; if one found such a spread in a small sample, it would be expected as a statistical matter that in the entire population of drugs there are some with spreads significantly larger than 400%. That is, since the study provides only a sample of spreads, it would be expected that for all drugs, the highest spreads exceed the highest spread observed in the sample.[54]

2. The ASCO Study

68. The ASCO study cited by Dr. Hartman was a critique of the Medicare payment methods and did not include any new survey of spreads. Nevertheless, had it been relied upon to form expectations on spreads during the damage period or if the survey reveals expectations of the payors, it would refute the key hypothesis of the Hartman Declaration, that class members expected the same spreads on all drugs and time periods.

> Although WAC represents the price at which manufacturers typically sell to wholesalers, *neither WAC nor AWP is necessarily a reliable guide to the price paid by the end user.*[55]
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> ***

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[53] "Physicians' Costs For Chemotherapy Drugs," OIG Study, Appendix II, 1992. p. 7.

[54] This general statistical principle was recognized by Dr. Berndt when he noted that "[t]he 'high touch, high cost' characteristic of the physician-administered drugs also implies that the statistical variance from any sample of information could be very high, further jeopardizing the reliability of any single information source." (Berndt Report at p. 53.)

[55] Reform of the Medicare Payment Methods for Cancer Chemotherapy, ASCO, May 2001. Emphasis added.

> ... payment amounts for drugs under state Medicaid programs and *private insurance plans assume that the AWPs are inaccurate ....*[56]

69. The studies clearly show that such competition increases spreads, and it is not appropriate to refer to them only to determine the spreads on drugs that do not face competition. As Dr. Hartman testified:

> Dr. Hartman:
> [A]nyone attempting to understand the results of a survey wants to look at...the results and look at the details. You will look at – you will look at all aspects of it that you can in order to be as informed as you can."[57]

3. *Other Public Studies*

70. Other public studies conducted by the OIG but not cited by Dr. Hartman also show that PADs had spreads in excess of 30% and that AWP was not a reliable indicator of acquisition costs.[58]

D. Contractual Reimbursement Rates

71. As his third source, Dr. Hartman argues that the range of payor expectations about the spreads for any single NDC can be determined by a review of the range of negotiated reimbursement rates between payors and physicians. He suggests there are two ways that such contracts reveal payor expectations. First, Dr. Hartman notes that the lowest reimbursement rate he identified for PADs was AWP -15% (this apparently means to him

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[56] ASCO Study, p. 37. Emphasis added.

[57] Hartman Deposition at 737:13-19.

[58] See, "Physicians' Costs for Chemotherapy Drugs," Department of Health and Human Services Office of Inspector General, November 1992; and "Excessive Medicare Payments for Prescription Drugs," Department of Health and Human Services Office of Inspector General, December 1997.

that spreads over ASP would be somewhat more that 15%).[59] Dr. Hartman then argues that since payors would intend to leave "some margin" for providers, contract reimbursement rates for the most favorably positioned payors are consistent with his conclusion that expectations for payor spreads could not exceed 30%.[60] He states also that his review of contracts demonstrates that TPPs have negotiated reimbursements for PADs in a range of AWP ± 15%, so that the maximum difference in reimbursement rates between any two payors is 30%.[61] The suggestion appears to be that this 30% variability in reimbursement rates reflects the variability in payor expectations.

72. In Attachment C of his December 2005 Declaration, Dr. Hartman presents only four contracts covering two payors. He says that this is also the range found by the MedPAC report of 2003 which, using data for 2002, showed that TPPs reimburse PADs on average of 97.5% of AWP (*i.e.*, AWP – 2.5%) with the range being 85% to 115%.[62]

73. I note that Dr. Hartman's data on reimbursement rates is limited and his sample does not define the population of contracts that existed throughout the class period. Thus, he cannot conclude statistically that the range of reimbursement rates for any payor did not exceed 30% during the class period. Indeed, statistics indicates that the range of the population of contracts would indeed exceed the range of the sample. Thus, Dr. Hartman should have concluded that the contract reimbursement rates *do not* provide support for the proposition that payor expectations of spreads never exceeded 30%.[63]

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[59] Hartman Declaration, December 15, 2005, FN62, p. 40.

[60] Hartman Rebuttal Declaration, December 16, 2004, p. 63-64.

[61] Hartman Declaration, December 15, 2005, p. 19.

[62] Hartman Declaration, December 15, 2005, pp. 16-17.

[63] With respect to generic drugs, some payors had reimbursement rates below 30%, indicating that they expected that spreads were in excess of 30%. See Hartman Deposition at 759:7-8, for a discussion of Cigna's reimbursement codes that are "up to 45% below AWP." In addition, starting in 2003 Colorado and Connecticut reimbursed generic drugs at AWP-35% and AWP-40% under their Medicaid programs.

74. More fundamentally, Dr. Hartman's theory that the reimbursement contracts "reveal expectations" about spreads for drugs facing therapeutic or generic competition is incorrect.

75. First, the contracts he reports apply a common reimbursement rate to a variety of drugs. Even if one accepted Dr. Hartman's argument that reimbursement rates reveal expectations about spreads, the contractual reimbursement rates would reveal only expectations about *average* spreads and would not inform what was the expected maximum spread for any drug or group of drugs. As a result, the range of discounts in the reimbursement contracts tells us nothing about whether payors expected a 30% limit to the range in the spread for all NDCs and all one year time periods.

76. Although Dr. Hartman does not clearly define what he means by a "market expectation," his analysis of reimbursement rates reveals only his personal expectation and the *minimum* expectation of payors. For example, consider those TPPs paying in the reimbursement range AWP + 15%. For these payors, we clearly know nothing about what they expected, since providers have captured the entire spread (whatever that may be) plus a premium of 15%. According to Dr. Hartman, other providers receive reimbursement rates as low as AWP - 15%, which tells us only that the spread must be *at least* be 15%, but again does not indicate how much higher it might be. Dr. Hartman's use of a 30% yardstick is connected to payor reimbursement contracts only by adding a subjective and arbitrary "some margin" to physicians receiving the 15% minimum observed in the most favorable (to payors) contracts identified by Dr. Hartman.[64] Thus, the yardstick reveals only Dr. Hartman's expectation, not any measure of "market expectations" objectively inferred from the contract data.

77. The problem is compounded by the fact that the reimbursement rates also simultaneously incorporate many other factors, as acknowledged by Dr. Hartman. An expected spread of 100% on ASP (that an ASP that is 50% of the AWP) can just as easily lead to a discount of 15% from an AWP, on average, as an expected spread of 30%. Payors may knowingly

[64] Hartman Deposition at 671:20, 697:13-698:3.

negotiate to permit physicians to retain some portion of the spread larger than the approximate margin assumed by Dr. Hartman. For example, the level of margin that the payors must leave to the providers is determined by their relative market power as well as the optimal composition of the network that payors wish to achieve. Thus, if the provider has significant market power and/or the payor must leave a generous margin to the provider in order to attract the provider to its network, it may agree to a contract reimbursing at a discount of 15% from an AWP even though the payor's expectation was that the physician received an average discount of 50% (or higher) of AWP from the manufacturer. In his rebuttal and damages reports, for example, Dr. Hartman attributes the full 30% range not to differences in expectations about drug spreads, but rather also to differences in relative bargaining power between payors and physicians and other factors:

> Dr. Hartman:
> [S]ome individual payors possess considerable bargaining power and are able to negotiate favorable reimbursement rates at AWP – 15% (*i.e.*, r^{ni}_{f} and r_{f} in Figure 1). Other commercial payors have little bargaining power and can only negotiate least favorable reimbursement rates at AWP + 15% (*i.e.*, r^{ni}_{lf} and r_{lf} in Figure 1). Other payors will fall in between.[65]
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> ***
>
> . . . some payors will be more successful in bargaining aggressively than others, given their size, strictness of their formularies and the number of lives they insure.[66]
>
> ***
>
> . . . there will be a bell-shaped curve [footnote omitted] summarizing payer reimbursement rates relative to the actual AWP. The position of a given payer on that bell-shaped curve will be determined by its relative size, bargaining strength, information and expectations.[67]

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[65] Hartman Declaration, December 15, 2005, p. 22.

[66] Hartman Declaration, December 16, 2004, p. 59.

[67] Hartman Declaration, December 16, 2004, p. 59.

78. Dr. Hartman has thus failed to test whether the market power of doctors is an "intervening factor" as noted by the Court.[68] This is curious because even in Dr. Hartman's view at least some of the spread income is not due to the alleged fraud but resides in the bargaining position of the physicians:

> Dr. Hartman:
>
> In order to avoid injury, a payor would need full information *and the market power to force all distributors to disgorge the overcharges paid as a result of the AWP scheme*. No single payer existed with that degree of knowledge *and that degree of market power*.[69]
>
> ***
>
> Q: So the desire to have an adequate provider network might be another reason why a payer would not change its reimbursement formula even though it had knowledge of actual ASPs; correct?
>
> A: I'm – I have not done enough of a study to be able to assess or respond to that...the particular monopoly power or the market power on this side of this negotiation in my view would be with the providers as opposed to the payors...."[70]
>
> ***
>
> There's market power by these specialists that provide these kinds of drugs. They are able to negotiate much more aggressively *vis-a-vis* – or refuse to accept certain positions, *vis-a-vis* a payer. They have market power. They are one of the few games in town.[71]

79. Dr. Hartman's revealed expectations theory could be tested empirically. If it is valid, one would expect statistically significant decreases in reimbursement rates over the class period as information about spreads allegedly became more wide spread. In fact, Dr. Hartman does not observe a large drop in reimbursement rates for contracts between payors and physician

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[68] Class Certification Order, p. 74.

[69] Hartman Rebuttal Declaration, December 16, 2004 at FN97, p.62.

[70] Hartman Deposition at 860:4-20.

[71] Hartman Deposition at 1041:8-13, regarding oncologists in upstate New York.

groups over time, which suggests his hypothesis is incorrect.[72,73] He notes that his review of the contract data suggests that contracts were being negotiated at a discount of 15% to 20% from AWP when the contemporaneously available reports suggested much larger spreads of 60% to 80%.[74]

80. Other data also are inconsistent with the theory that reimbursement rates would change in response to information about spreads. For example, plaintiff Blue Cross Blue Shield of Massachusetts's (BCBSMA) Mr. Mulrey testified that BCBSMA estimated it could save millions annually by switching to ASP-based pricing. Despite those savings, BCBSMA has decided to leave its reimbursement rate for PADs unchanged at AWP-5%.[75] Presumably, its expectations about spreads presently are relatively accurate, yet reimbursement rates are unchanged. Mr. Mulrey noted that one consideration could be keeping providers in its network.[76]

81. Faced with data that reimbursement rates have not changed over time in response to new information about spreads, that should have caused him to reject his theory, Dr. Hartman proposes an alternative theory that he fails to test. Dr. Hartman argues that current contracts do not reflect allegedly new information on spreads because of a series of lags: 1) the time required for a relatively small item such as PADs to get on the "radar screen" of something

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[72] Because reimbursement rates differ across payors and physician groups, the relevant comparison is the reimbursement rate for a particular physician group over time, and controlling for other factors that may affect reimbursement rates.

[73] Regarding whether studies showing spreads for single and multi-source drugs informed payor expectations about the relationship between spreads and AWP, Dr. Hartman testified that: "So in answer to your question, there is some information there, but it is, as far as I can see from the contracts and everything else, *this did not affect what – how Medicare was ending up setting its reimbursement rates nor how third-party payer were.*" (Hartman Deposition at 731:17-22) He testified also: "So this kind of information, it was starting to pop up, but this was not shaping general expectations as I see in contracts and in revealed preferences from the sources that I have cited." (Hartman Deposition at 733:4-8)

[74] Hartman Deposition, pp. 197-205 and pp. 218-219.

[75] Deposition of Michael T. Mulrey, January 5, 2006 at 71:22-72:10 & 137:5-11.

[76] Deposition of Michael T. Mulrey, January 5, 2006 at 129:22-130:12.

that needs to be managed; 2) the time required for cumulative evidence of increased spreads to be perceived as a pattern; and 3) the time required for the cumulative evidence to be embodied in contracts that incorporate reimbursement formula that are "hard wired" due to "*status quo* bias."[77]

82. Dr. Hartman's rejection of reimbursement contracts as indicators of changing expectations means that, by his own admission, he has no reliable evidence to confirm his "market expectations yardstick" for liability. In addition, his damage theory is completely divorced from any reliable and contemporaneous evidence on expectations, and we are left only with Dr. Hartman's assertion that his theories will be supported by changing reimbursement rates at some future time.[78]

E. Economic Logic

83. Dr. Hartman's theory that payors would not expect spreads to increase as competition for a new drug enters is not plausible as a matter of economic logic. AWPs clearly are visible to payors through claims data and published sources. For example, suppose payors observe that the AWP for a single-source innovator drug remains the same or increases over time. Over that same period, payors also can observe that therapeutic competitors enter and later that generic competitors enter. Dr. Hartman's assumption requires that payors did not expect that selling prices would drop in the face of such new competition and that, indeed, if the AWP increased over time, the selling price must have increased correspondingly. He provides no evidence that payors lacked the simple intuition that prices would decline once a monopoly provider faced competition, as would be expected in virtually any market. Indeed, Dr. Hartman himself argues and cites evidence that it was widely understood that

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[77] Hartman Deposition at 840:19, 932:20-933:2, 936:10-937:5, 945:1-20, 947:15-948:3, 956:10-18, 957:14-959:3, 972:15-973:3, 973:12-974:20, 977:4-979:10, 1003:2-12. Professor Meredith Rosenthal, another witness for the class, agrees. At her deposition at 104:15-22, she says: "There's a feasibility concern ... it's very arduous to change claims systems to adapt to a new set of information."

[78] Hartman Deposition at 958:15-17: "That doesn't mean that they're not going to reveal their preferences a year from now ...."

ASPs for self-administered drugs fell dramatically as generic competition entered the market:

> Dr. Hartman:
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> [O]nce a generic launches, its AWP usually remains constant (or may increase slightly), *while the ASP of the drug is known to decline precipitously with multiple generic launches over time, relative to the pre-generic-launch branded price and, by implication, relative to the generic AWP...[T]his pattern for generic prices is well known* and has been well-documented in the scientific peer-reviewed literature...[79]
>
> ***
>
> For generic drugs, once generic manufacturers announce their AWP (the first generic manufacturer with 180-day exclusivity always announces first), the generic manufacturers compete on ASP in order to move market share. The prices (ASPs) of generic drugs follow *a predictable trajectory* from the pre-generic launch brand-name price (and from the generic AWP) toward variable production cost as more generics come into the market; see the many analyses in footnote 62.[80]

84. Dr. Hartman, however, states that this widely understood expectation applied only to self-administered drugs because physician administered multi-source drugs were "less scrutinized or understood."[81] Even if true, the lack of information does not compel or even support the conclusion that payors expected their spreads to be the same as monopoly drugs and relied on that expectation in their negotiations.

85. It is also curious that Dr. Hartman ignores the fact of higher spreads even for generic and self-administered drugs at issue in this case. For example, I understand that Albuterol manufactured by Warrick, a drug for which Dr. Hartman finds liability and damages using his yardstick, was generic and primarily self-administered.[82]

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[79] Hartman Rebuttal Declaration, December 16, 2004, p. 39.

[80] Hartman Rebuttal Declaration, December 16, 2004, FN95, pp. 66-67.

[81] Hartman Deposition at 965:8-966:7.

[82] Declaration of Harvey J. Weintraub.